

INSIGHTEC

**SAFE.
EFFECTIVE.
LIFE-CHANGING.**

Tremor can take away a person's independence, self-esteem and the freedom to live an active life. Exablate Neuro uses focused ultrasound, an incisionless treatment, guided by MRI, to treat tremor patients with both immediate and long-lasting results.



FOCUSED ULTRASOUND

Incisionless Outpatient Procedure

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Focused ultrasound offers a next generation incisionless outpatient procedure for patients with Essential Tremor or Parkinson's Disease who don't get acceptable tremor relief from medications.

With no incisions or implants, there is little to no risk of infection and patients usually return home the same day.

Benefits for your Patients



Incisionless treatment

- Treatment available on both sides (staged, unilateral with 9 months separation) for ET patients
- No invasive burr holes or implants
- No general anesthesia required
- Little to no risk of infection¹
- Minimal hospitalization



Tremor improvement

- Immediate tremor improvement post-procedure
- Improved quality of life¹ and functional disability²
- Durable tremor improvement maintained to at least 5 years for first side¹ and to 6 months for second side²



Personalized treatment

- Neurologic evaluation of patient response and potential side effects before final lesion
- Enables sub-millimeter target movement



Safe and effective

- Real-time thermal feedback to continuously monitor patient safety and temperature at target
- Majority of adverse events were mild and moderate^{1,2}

Thermal ablation of the ventral intermediate nucleus (Vim) of the thalamus is done under MR guidance for visualization of patient anatomy, real-time thermometry as well as immediate confirmation of treatment outcome. During the procedure, patients are awake and responsive to assist in evaluating response including tremor improvement and potential side effects. Many patients report immediate and lasting improvement of the tremor in their treated hand with minimal complications.



I just wanted a chance to get my life back. I was shaking so much. Nobody knows what that's like, unless you've lost a part of your life and then you regain it. I'm so thankful.

Carol Klein*, Focused Ultrasound Patient



Focused Ultrasound has really revolutionized our treatments of tremor, because patients are now coming in and asking for focused ultrasound.

Andres Lozano, MD**, University of Toronto, NeuroNews July 2021



I was just floating [in the MRI]. It was the most peaceful feeling. That's when I knew those tremors were gone. That peace I felt was unbelievable.

Marie Baker*, Focused Ultrasound Patient

¹Premarket Approval P150038, CE mark received
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038>

²Premarket Approval P150038-S022, CE mark received
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038S022>

*This patient testimonial may not be representative of all treatment outcomes.

**Dr. Lozano is a paid consultant for Insightec for educational and research purposes. Toronto Western Hospital at the University of Toronto participates in Insightec-sponsored clinical trials, including those listed in this document.

TRANSFORMING PATIENT CARE

Exablate Neuro

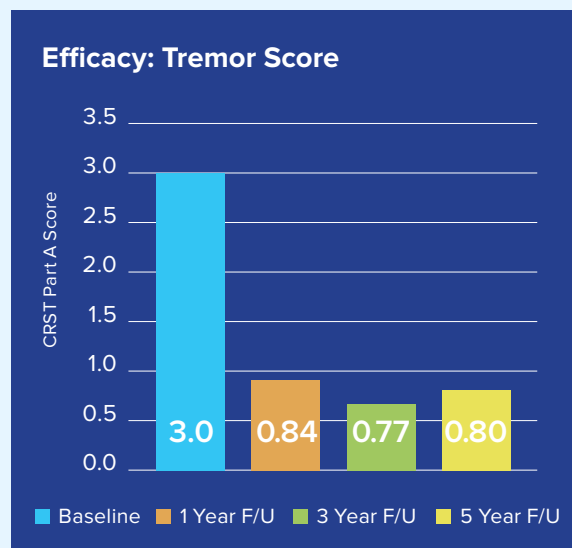
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Facts About Focused Ultrasound

- The procedure was FDA approved for the first side of Essential Tremor patients in 2016, and CE marked in 2012 with over 12,000 procedures performed worldwide since approvals. The second side procedure was FDA approved in 2022, and CE marked in 2023.
- Exablate Neuro is covered by Medicare in all 50 states for essential tremor unilateral treatment. Aetna, CIGNA and Humana cover treatment for essential tremor unilateral treatment nationally, and 80% of Blue Cross Blue Shield plans provide access for essential tremor unilateral treatment. Please contact your treatment team for coverage information on Second Side treatment.
- Focused ultrasound treatment is patient specific. Treatment starts with low energy, which is gradually increased to optimize tremor relief and minimize side effects.
- Focused ultrasound is available and offered at treatment centers throughout the country. For more information, visit our website: insightec.com/global/treatment-centers/

Clinical Evidence: First Side tremor reduction (CRST Part A) greater than 70% maintained to 5-year study conclusion

5-year follow-up of 40 subjects in the pivotal study of focused ultrasound for essential tremor showed over a greater than 70% tremor reduction maintained to the study conclusion. ¹



Safety: No serious adverse events at 5-year study conclusion

- The most common adverse events reported by subjects in Insightec-sponsored clinical studies after treatment included: imbalance/gait disturbance (26% of study patients), numbness/tingling (33%), and headache/head pain (51%).
- Most complications were classified as mild or moderate, and 48% resolved on their own within 30 days. At the 5 year conclusion of the study, the only adverse event remaining in more than 5% of study subjects was paresthesia (n=8, 20%), and all cases were mild or moderate. No new adverse events and no serious adverse events were observed between 1 and 5 years. At the study conclusion, additional less frequent events included unsteadiness, limb weakness, gait disturbance, dysmetria, dysgeusia, slow movement, and head pressure.
- Patients should discuss in detail the risks, benefits and treatment options with their physician prior to treatment. For more safety information, please go to <https://insightec.com/safety-information>

*Data on file with Insightec. Premarket Approval P150038-S022, CE mark received.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038S022>

Note: The system may only be operated by licensed physicians that have successfully completed the Exablate training program.

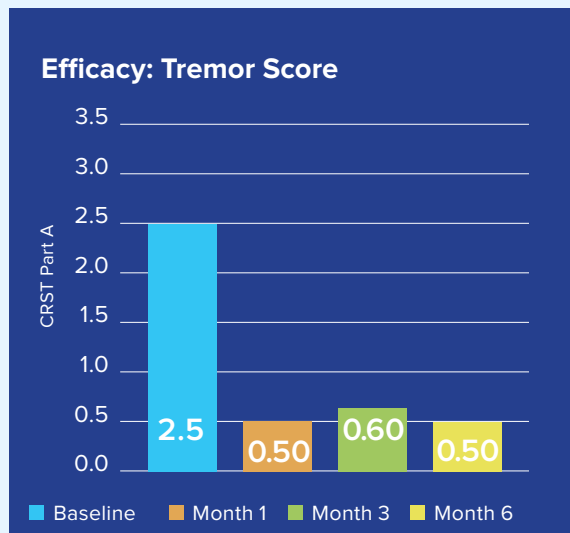
TRANSFORMING PATIENT CARE

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Clinical Evidence: Second Side tremor reduction (CRST Part A) greater than 80% sustained at 6 months

Follow-up of 51 subjects in the pivotal study of focused ultrasound for essential tremor for the contralateral side showed greater than 80% postural tremor improvement sustained to the 6-month time point.²



Safety: 98% mild or moderate adverse events

The safety profile of the second side treatment is similar to the safety profile of the treatment of the first side. In an Insightec-sponsored clinical study that included 51 subjects at seven leading academic medical centers in the US, 85% of the adverse events reported were mild, and 98% were mild or moderate.

During procedure or within 24 hours:

There was one procedural related serious adverse event - a urinary tract infection following the use of a catheter during the procedure.

In the clinical study, the most common adverse events that occurred during the procedure or within the first 24 hours were:

- Numbness / Tingling (33.4% of 51 subjects)
- Dysarthria (29.4%)
- Ataxia (23.5%)
- Unsteadiness / Imbalance (19.6%)
- Dysgeusia (13.7%)

Less frequent events that occurred in 2-10% of subjects included gait disturbance, dysphagia, hypogeusia, dysmetria, fatigue.

Ongoing side effects at 6 months:

At 6 months, there were no serious adverse events, and the only moderate adverse events were 1 case of dysgeusia and 1 case of dysphagia. One subject missed the 3-month and 6-month checks. The most common adverse events (all mild) that were still ongoing in the 50 remaining subjects at 6 months included:

- Numbness / Tingling (16.0% of 50 subjects)
- Dysarthria (14.0%)
- Ataxia (14.0%)

Less frequent events that occurred in 2-8% of patients included dysgeusia, hypogeusia, and dysphagia.

No new adverse occurred between 1 and 6 month timepoints of the trial. Events that were observed in a single subject are not listed (= to 1.96% of subjects).

Patients should discuss in detail the risks, benefits and treatment options with their physicians prior to treatment. For more safety information, please go to <https://insightec.com/safety-information>

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